SEP 2 0 2002

K022912

Attachment I
510(K) Summary
BASIC Dental Implant System Post and Core - Thin Attachment

This 510(K) Summary of safety and effectiveness for the BASIC Dental Implant System Post and Core – Thin Attachment is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	BASIC Dental Implant Systems, Inc.
Address:	3321 Columbia NE Albuquerque, New Mexico 87107 USA
Contact Person:	Dan Blacklock, Vice-President
Telephone / Fax / Email	505.881.1376 – Phone 505.884.1923 – Fax
Preparation Date:	August 28, 2002
Device Trade Name:	BASIC Dental Implant System Post and Core – Thin Attachment
Common Name:	Accessory to a Dental Implant
Classification:	DZE
Legally Marketed Predicate Device:	BASIC Dental Implant System Post and Core Attachment K number K960868
Description of the Post and Core – Thin Attachment:	The Post and Core – Thin Attachment is a one-piece attachment. The base is cemented into a dental implant. Artificial teeth are then attached to the Post and Core - Thin using conventional techniques.
Intended use:	The Post and Core - Thin Attachment is intended to attach artificial teeth to a dental implant.
Performance Data:	None
Results of Clinical Study:	None
Conclusion:	The Post and Core–Thin attachment is substantially equivalent to other existing Post and Core attachments in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2002

Mr. Dan Blacklock
Vice President
BASIC Dental Implant Systems, Incorporated
3321 Columbia NE
Albuquerque, New Mexico 87107

Re: K022912
Trade/Device Name: BASIC Dental Implant System Post & Core-Thin Attachment
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: August 28, 2002
Received: September 3, 2002

Dear Mr. Blacklock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Patricia Cecere/for

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: ~~Pending~~ K022912

Device Name: BASIC Dental Implant System Post & Core – Thin Attachment

Indications for Use:

The BASIC Dental Implant System Post & Core – Thin Attachment is indicated for attaching artificial teeth to a dental implant.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022912